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|--|-------------|----------------------|---------------------------------|-----------------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
| 10/766,068   | 01/28/2004  | Soichi Saito         | WAKAB85.001AUS                  | 2422                        |
| 20995 7590 10/20/2008<br>KNOBBE MARTENS OLSON & BEAR LLP<br>2040 MAIN STREET<br>FOURTEENTH FLOOR<br>IRVINE, CA 92614 |             |                      | EXAMINER<br>OLSEN, KAJ K        |                             |
|  |             |                      | ART UNIT<br>1795                | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>10/20/2008 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/766,068 | <b>Applicant(s)</b><br>SAITO ET AL. |  |
|                              | <b>Examiner</b><br>KAJ K. OLSEN      | <b>Art Unit</b><br>1795             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11 and 14-20 is/are allowed.
- 6) ☒ Claim(s) 12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. In claims 12 and 13, applicant has amended the claims to specify that the presence of a system for detection of the position of the sensor such that the sensor is installed in a position where the sensor is immersed in the buffer solution. The examiner is unclear if applicant has support for this limitation in the originally filed disclosure. In particular, the only mention of such a detection system is the vague reference to the sensor being immersed in a storage liquid as “detected by the lead switch, and the like” (p. 37, last two lines of the page). It is unclear from this vague mention on p. 37 if the lead switch is detecting the position of the sensor or is merely specifying that the sensor response is detected by the lead switch. The examiner does not believe this sufficiently supports this new limitation.

4. Moreover new matter issues aside, this new limitations of claims 12 and 13 is not sufficiently enabled for this new limitation. What is a lead switch and how can it be utilized as a

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detection means for the position of the sensor? How can the lead switch detect the difference between a buffer or storage solution and a sample solution (if at all) and hence determine the position of the sensor? The specification appears to be silent on these questions.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In the new limitations of claims 12 and 13, there is no antecedent basis for “the holding time”. There is a previous mention of “holding the chemical sensor in a standby state” (claim 12) or “holding the chemical sensor in the buffer solution” (claim 13), but no reference to time being affiliated with either of these phenomenon.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inamoto et al (USP 5,352,349) in view of Cozzette et al (USP 5,112,455) and White et al (USP 5,352,351). White is being cited and relied on for the first time with this office action. Its use was necessitated by the applicant's amendment to the claims.

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10. Claims 12 and 13 remain rejected over the teachings of Inamoto and Cozzette for the reasons set forth in the 9/28/2007 office action and further clarified in the 4/11/2008 office action. Applicant has amended these claims to further specify software to automatically control the setting of the applied bias and the holding time (presumably the amount of time the bias is to be applied (see the 112 rejection above)). However, it is noted that Inamoto disclosed that the both the biases and the amount of time the biases are to be applied can be suitably controlled by a control section 18. See col. 8, ll. 9-57 for the discussion of the controlling of time and biases and see col. 10, ll. 65 and 66 for the discussion of the control section. Although Inamoto does not explicitly disclose this control section utilize software for the control, one possessing ordinary skill in the art would clearly recognize that a software controller microcontroller would be an obvious means for controlling the biases to be applied to the electrodes as well as the holding time for these biases. With respect to the new limitation “in accordance with said procedure for initial treatment”, the examiner is not interpreting this limitation as further defining the software itself and is only specifying what procedure the software is to be utilized with. The software limitation is only specifying the setting of the applied bias and the holding time, which would have been an obvious variant means for Inamoto to control its bias and holding times as discussed above.

11. With respect to the presence of a system for detection of the position of the sensor, Inamoto does not disclose detecting the position of the sensor. Although it is unclear to the examiner how said function is disclosed or enabled by the present invention (see 112 rejection above), it is known in the art to monitor whether the sensor is in a measurable fluid or not. In particular, White demonstrates that one can monitor the current at a measuring electrode to

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determine if the electrode is in the presence of a fluid sample or not. See col. 5, ll. 1-18. This would read on the broadly defined system for detection of position of the sensor because this monitored current indicates that the biosensor has been solvated with a fluid whether the fluid be a sample solution or a buffer solution. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of White for the apparatus of Inamoto and Cozzette because the system of White is a simple means for ensuring that the sensor is appropriately solvated with fluid before performing the suite of voltage pulses disclosed by Inamoto. Although the system of White cannot determine the difference between a buffer solution and a sample solution, it is unclear from applicant's disclosure whether the present invention can differentiate these two different fluids either.

***Allowable Subject Matter***

12. Claims 1-11 and 14-20 are allowed for the reasons set forth in the 4/11/2008 office action.

***Response to Arguments***

13. Applicant's arguments with respect to claims 12 and 13 have been considered but are moot in view of the new ground(s) of rejection.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/  
Primary Examiner, Art Unit 1795

October 17, 2008